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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,363	07/19/2001	Andrew L. Feldhaus	226272003802	5021

25226 7590 07/15/2003

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EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/15/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,363

Applicant(s)

Feldhaus

Examiner

Mosher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/3/2003, 4/3/2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-99 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 52-57, 71-79, and 92-94 is/are allowed.
- 6) ☒ Claim(s) 36-51, 58-70, 80-91, and 95-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 13 6) ☐ Other:

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DETAILED ACTION

Specification

The amendment filed March 3, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the change of application 08/445,552 to 08/455,552. This is seen as introducing new matter, for the following reasons. All of the changes to page 6, line 7, are corrections of obvious errors, because it would have been clear to one skilled in the art that citation information was omitted, and because the incomplete information originally presented would have been sufficient to permit one skilled in the art to unambiguously identify the intended citation (e.g. by consulting the Medline database using the available information regarding author, publication date and subject matter). Therefore, both the error and the correction would have been apparent to one skilled in the art, for the incomplete or erroneous citations. However, for the pending patent application, the specification only discusses the subject matter of the copending application and states that it is commonly owned. Since neither this application nor the parent application has any record of assignment, there is no way to determine what applications were commonly owned at the time of filing, and therefore no way to determine which application was the correct one. Therefore, even if it was apparent that the wrong application was cited, it was not apparent what the right application should have been. Therefore, this change is not a mere correction of an obvious error. Since the specification incorporates by

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reference all publications and applications cited, the change in the application number introduces new matter into the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 36-51, 58-70, ~~81~~⁸⁰-91, 95-99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36 and 64 require "a human transcriptionally active element." This is ambiguous, as it could reasonable be interpreted as "an element active in human cells" or as "an element from a human gene." These are different in scope. Both interpretations are consistent with the specification, as there is an overall intent to express things in human cells, and there are examples where promoter elements were obtained from human genes. Since applicant points to support for claim 36 in examples which use elements obtained from human gene promoters, the examiner assumes that the intent is the second interpretation. This could be clarified by amending the claims to recite "a transcriptionally active element from a human gene promoter." This problem affects dependent claims 37-51, 65-70, 89-91, 98, and 99.

Claims 58 and 80 contain the recitation "comprises one or more transcriptionally active elements which are removed from a promoter." This recitation is confusing, since it requires the element to be both present and removed. On close reading of the same recitation on specification page 24 and the working examples, it appears that this phrase means that the element is removed

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from the context of its original promoter and inserted in the AAV construct. Is this the intent of these claims? This affects dependent claims 59-63, 81-88, and 95-97

To summarize the examiner's understanding of the intent of the new claims, the new claims specify that the heterologous elements are obtained from a human gene promoter (claims 36-51, 64-70, 89-91, 98, and 99), or that the expression is tissue specific and the non-AAV element has a deletion compared to its native sequence (claims 52-57, 71-79, 92-94) or the expression is tissue specific and the non-AAV element is removed from the context of its native promoter sequence (claims 58-63, 80-88, and 95-97). Please confirm for the record if this claim is correct.

Allowable Subject Matter

Claims 52-57, 71-79, 92-94 are allowed. Claims 36-51, 58-70, 81-91, and 95-99 are free of the prior art (if interpreted as indicated above). The prior art does not teach or suggest constructs with the particulars of the transcriptionally active elements as recited in the claims, within the size limitations required by the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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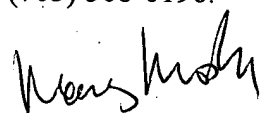
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone numbers for this Group are now (703) 872-9306 for Before Final responses, and (703) 872-9307 for After Final responses. Faxes for this Group can also be sent to (708) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 14, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600 1600